



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-1019]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Integrating Community Pharmacists and Clinical Sites for Patient-Centered HIV Care (OMB No. 0920-1019, Expires 05/31/2017) - [Revision] - National Center for HIV, Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Revisions to this information collection include the addition of an Interviewer data collection worksheet, Key Informant Interviewer script, Staff communication questionnaire, Clinic cost form and Pharmacy cost form. These additions are needed in order to determine changes to clinic and pharmacy work systems, processes and outcomes in relation to the model project and how and if the model program improves patient outcomes through improved communication and collaboration between patients' clinical providers and pharmacists. In order to determine the general feasibility of the model program, the time required conducting program activities and the associated cost of program activities must be determined. Collection of data from the previously approved Initial patient information forms, Quarterly patient information forms, Pharmacy record abstraction forms, Project clinic characteristics forms, and Project pharmacy characteristics forms is ongoing. Clinic staff will use the initial information Sheet to explain the project to patients.

CDC has entered into a partnership with Walgreen Company (a.k.a. Walgreens pharmacies, a national retail pharmacy chain) and the University of North Texas Health Science Center to develop and implement a model of HIV care that integrates community pharmacists with primary medical providers for patient-centered HIV care. The model program will be

implemented at ten sites and will provide patient-centered HIV care for approximately 1,000 persons.

The patient-centered HIV care model includes the core elements of pharmacist provided Medication Therapy Management (MTM) as well as additional pharmacist services such as individualized medication adherence counseling, active monitoring of prescription refills and active collaboration between pharmacists and medical clinic providers to identify and resolve medication related treatment problems such as treatment effectiveness, adverse events and poor adherence. The expected outcomes of the model program are increased retention in HIV care, adherence to HIV medication therapy and HIV viral load suppression.

Pharmacy, laboratory and medical data are collected through abstraction of participant clients' pharmacy and medical records. These data are needed to monitor retention in care, adherence to therapy, viral load suppression and other health outcomes. Program specific data, such as the number of MTM elements completed per project site and project sites' characteristics, will be collected by project sites.

This information collection will allow CDC to conduct continuous program performance monitoring which includes identification of barriers to program implementation, solutions

to those barriers, and documentation of client health outcomes. Performance monitoring will allow the model program to be adjusted, as needed, in order to develop a final implementation model that is self-sustaining and which can be used to establish similar collaborations in a variety of clinical settings. Collection of cost data will allow for the cost of the program to be estimated. There is no cost to participants other than their time. The total estimated annualized burden hours are 6,043.

Estimated Annualized Burden Hours

Type of respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Clinic Data Manager	Project clinic characteristics form	10	3	30/60
Pharmacist	Project pharmacy characteristics form	10	3	30/60
Clinic Data Manager	Patient Demographic Information form	10	100	5/60
Clinic Data Manager	Initial patient information form	10	100	1
Clinic Data Manager	Quarterly patient information form	10	400	30/60
Pharmacist	Pharmacy record abstraction form	10	400	30/60

Key informants	Interviewer data collection worksheet	60	2	30/60
Project pharmacists and clinic staff	Staff communication questionnaire	70	2	15/60
Clinic staff	Clinic cost form	20	2	10
Pharmacy staff	Pharmacy cost form	20	2	10

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